In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: July 30, 2020

KAVITA DESAI,	*	UNPUBLISHED
	*	
	*	No. 14-811V
Petitioner,	*	
v.	*	Special Master Gowen
	*	
	*	Ruling on Entitlement; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA).
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for petitioner.
Camille M. Collett, Department of Justice, Washington, D.C., for respondent.

RULING ON ENTITLEMENT[1]

On September 4, 2014, Kavita Desai ("petitioner"), filed a petitioner for compensation under the National Vaccine Injury Compensation Program.[2] Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA") as a result of receiving an influenza ("flu) vaccination on November 15, 2012. Petition at Preamble. (ECF No. 1). Based on a full review of all the evidence and testimony presented at the entitlement and damages

[1] Pursuant to the E-Government Act of 2002, *see* 44 U.S.C. § 3501 note (2012), because this opinion contains a reasoned explanation for the action in this case, I am required to post it on the website of the United States Court of Federal Claims. The court's website is at http://www.uscfc.uscourts.gov/aggregator/sources/7. **This means the opinion will be available to anyone with access to the Internet.** Before the opinion is posted on the court's website, each party has 14 days to file a motion requesting redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). An objecting party must provide the court with a proposed redacted version of the opinion. *Id.* **If neither party files a motion for redaction within 14 days, the opinion will be posted on the court's website without any changes.** *Id.*

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended 42 U.S.C. §§ 300aa-10 to 34 (2012) (hereinafter "Vaccine Act" or "the Act"). Hereinafter, individual section references will be to 42 U.S.C. § 300aa of the Act.

hearing held in Washington, D.C. on July 17-18, 2018, I find the petitioner is entitled to compensation.[3]

I. Procedural History

On September 4, 2015, petitioner filed her petitioner alleging that the flu vaccine was the cause-in-fact of her developing a right shoulder injury. Petition. This case was originally assigned to the Special Processing Unit ("SPU"). Petitioner filed medical records and a statement of completion on September 9, 2014, pursuant to the SPU Initial Order. *See* Petitioner's ("Pet.") Exhibits ("Ex.") 1-8 (ECF No. 6); Statement of Completion (ECF No. 7). After an initial status conference, petitioner filed an affidavit explaining that there are limited physical therapy treatment records for the time when she was India. Pet. Ex. 9.

On October 27, 2014, the case was reassigned to the undersigned's docket. *See* Notice of Reassignment (ECF No. 12). The undersigned held a status conference on November 20, 2014. During the status conference, respondent's counsel indicated that the site of vaccine administration was not clear in the record provided by the petitioner and that the onset of petitioner's symptoms was uncertain. *See* Order, issued on Nov. 20, 2014. (ECF No. 15).

On December 10, 2014, respondent filed a status report stating that petitioner's claim has "two deficiencies." Status Report (ECF No. 16). Respondent stated that "the applicable vaccine record conflicts with petitioner's allegation regarding the arm in which she received the vaccine. The vaccination record documents the site of administration of petitioner's influenza vaccine as the left deltoid. Pet. Ex. 1 at 1. Petitioner alleges that she received the vaccine in the right upper arm." *Id.* at 1. Respondent also stated, "The second deficiency in petitioner's case is an onset issue. The first documentation of petitioner's alleged vaccine-related "shoulder-pain" is three months post-vaccination when she first sought treatment for pain." *Id.* at 2. Petitioner was ordered to file outstanding medical records and affidavit relating to the administration of the flu vaccine and the onset of her shoulder pain. Scheduling Order (Non-PDF), issued on Dec. 18, 2014.

On January 28, 2015, petitioner filed a one-page record from petitioner's primary care provider which stated that that on November 15, 2012 - the day petitioner received the flu vaccination – petitioner had a "routine follow up and health screening," also described as a "routine general medical examination." Pet. Ex. 11 (ECF No. 17). During a status conference on February 20, 2015, the undersigned granted petitioner additional time to obtain any other records and directed petitioner to then convey a demand to respondent. Order (ECF No. 19).

The parties engaged in unfruitful settlement discussions through the first half of 2015. On June 25, 2015, respondent filed a status report stating that "petitioner has submitted a demand to respondent wherein petitioner indicates that she will not consider a discount of her damages based on a litigative risk analysis. Respondent's position continues to be that fundamental factual issues in this case need to be resolved." Status Report (ECF No. 24). A status

[3] Pursuant to §300aa-13(a)(1), in order to reach my conclusion, I considered the entire record, including all of the medical records, statements, expert reports, medical literature and testimony presented at the entitlement hearing submitted by both parties. This opinion discusses the elements of the record I found most relevant to the outcome.

conference was held on July 30, 2015. *See* Order, issued on Aug. 11, 2015. Petitioner requested a fact hearing during this status conference. *Id.* A fact hearing was scheduled for two days in November 2016. *See* Scheduling Order (ECF No. 33).

On September 14, 2015, petitioner filed a status report indicating that she had "filed all records from Jacobi Medical Center." Petitioner did not address the issue of insurance records. She requested more time to obtain additional records of her medical care in India. Status Report (ECF No. 27). On January 19, 2016, petitioner filed records from physical therapy treatments beginning on February 27, 2013. Pet. Ex. 12 (ECF No. 32)

Then, on March 2, 2016, respondent filed a status report stating that respondent's counsel had received authority to resolve the case on a litigative risk basis, but asked to preserve the hearing dates. Status Report (ECF No. 34).

Over the next approximately 11 months, the parties endeavored to resolve the matter informally. In support of her claimed future medical expenses, petitioner filed additional medical records and a life care planner's cost analysis. Petitioner also filed documentation relating to her lost wages claim, including her curriculum vitae indicating that she obtained her medical degree in India and was working as a clinical researcher in New York, New York. *See* Pet. Ex. 23 (ECF No. 57). In September 2016, the parties and the undersigned agreed to cancel the November 2016 hearing date.

Another status conference was held on December 7, 2016, where the parties discussed the impasses to settlement. Scheduling Order (ECF No. 52). On February 7, 2017, the undersigned held a status conference and agreed to schedule a hearing for July 17-18, 2018, to cover entitlement (including in which arm the vaccine was given, whether petitioner developed SIRVA and when her symptoms began) and damages (particularly those related to petitioner's lost wages). Order (ECF No. 59). The undersigned held a status conference on January 18, 2018, where the parties were a provided a list of issues that needed to be addressed to narrow the issues for the entitlement and damages hearing set for later that year. *See* Status Conference Order (ECF No. 88).

The next status conference was held on January 29, 2018. It was digitally recorded at respondent's request. The parties and the undersigned discussed the steps necessary before the hearing on entitlement and damages set for July 17-18, 2018. Petitioner advised that she was no longer claiming lost wages. Petitioner proposed traveling to the United States to meet with her treating orthopedist and the parties' life care planners, in advance of the hearing. Respondent stated that petitioner had refused his counter-offer, and that typically entitlement is resolved before damages. The undersigned indicated his preliminary and tentative view that petitioner was entitled to compensation for a right shoulder injury. Respondent requested that if the undersigned determined he had sufficient evidence to resolve entitlement, the undersigned should issue a written ruling on the same.

Respondent filed his Rule 4(c) report on February 23, 2018. Respondent's ("Resp.") Report ("Rept.") (ECF No. 93). Respondent stated that after reviewing the petition and accompanying documents, the Division of Injury Compensation Programs at the Department of

Health and Human Services, opined that this case [was] not appropriate for compensation. Resp. Rept. at 1. Respondent noted that petitioner filed her claim prior to SIRVA being added to the Vaccine Injury Table. *Id.* at 8. Respondent stated that petitioner's case does not meet the Table criteria "because the contemporaneous medical records do not support the onset of pain within forty-eight hours of vaccination." *Id.* Further, respondent argued that "the applicable vaccine record conflicts with petitioner's allegation regarding the arm in which she received the vaccine." *Id.* at 9. Respondent stated, "The vaccination record documents the site of administration of petitioner's influenza vaccine as the left deltoid. Petitioner alleges that she received the vaccine in the right upper arm." *Id.* Respondent stated that petitioner must prove by preponderant evidence that her November 15, 2012 flu vaccination actually caused her right shoulder injury. *Id.* at 9. Respondent concluded that petitioner has not submitted medical record evidence or a medical opinion to meet her burden under the Vaccine Act and the case should be dismissed. *Id.* at 10.

Petitioner filed additional medical records and a life-care plan. Pet. Exs. 27-29. Respondent filed an expert report by Dr. David Ring, M.D., PhD[4] on July 12, 2018. Resp. Ex. A. Petitioner filed the CV of Ms. Liz Kattman, petitioner's life care planner and additional medical records on July 13, 2018. Pet. Exs. 24 & 35. Through the prolonged history of this case the parties had addressed issues such as in which arm the injection was given; the onset of petitioner's pain and limitation of motion; and the nature of her ongoing symptoms. Accordingly, it was proposed that Dr. Ring would address the nature of the petitioner's ongoing symptoms and their relatedness to the vaccination.

On July 11-12, 2018, the undersigned held two status conferences in this case. The undersigned noted that Dr. Ring's report provided his opinion regarding the causation of petitioner's original shoulder injury and the relatedness of petitioner's original shoulder injury to petitioner's current pain and limitations, which was significantly untimely coming a week before trial and in light of the history of this case. Order (ECF No. 117). The undersigned explained that he intended to exclude Dr. Ring's opinion relating to the causation of petitioner's injury but allow testimony relating to the nature of petitioner's ongoing pain and limitations and relatedness to the vaccination. *Id.* at 3. At the entitlement hearing, respondent made an oral motion to allow Dr. Ring's full testimony to be considered, including on the issue of causation. Tr. 4-11. I granted respondent's motion with the proviso that the petitioner would have the opportunity to

[4] Dr. David Ring is an orthopedic surgeon, in Austin, Texas. Resp. Ex. A at 1; Resp. Ex. B. Dr. Ring received his undergraduate degree from University of California, San Diego in 1989. He attended the University of California at San Diego for medical school. *Id.* Dr. Ring was an intern of surgery at Massachusetts General Hospital and he completed a residency in orthopaedic surgery at Harvard Combined Orthopaedic Residency. *Id.* In 2000, he completed a hand and microvascular surgical fellow at Massachusetts General Hospital. Resp. Ex. B at 1. From 1999 through 2016, Dr. Ring taught orthopaedic surgery at Harvard Medical School. *Id.* At the time of the hearing, Dr. Ring was the Associate Dean for Comprehensive Care at Dell Medical School-The University of Texas a Austin. *Id.* He been on the editorial board of multiple medical journals and served as ad-hoc reviewer for other peer review medical journals. Resp. Ex. B at 8-9. Additionally, Dr. Ring has authored numerous peer reviewed publications. *Id.* at 41-3. During the hearing, Dr. Ring testified that he had not previously testified as an expert in the Vaccine Injury program, but has testified as an expert witness in state court. Tr. 254—55. Petitioner did not object to Dr. Ring being admitted as an expert in the field of orthopedics and psychiatry, and therefore, I admitted him as an expert in those fields. Tr. 255.

submit an expert report within sixty days of the conclusion of the hearing. Dr. Ring testified to the issues of entitlement. Tr. 236.

A hearing on entitlement and damages hearing was held on July 17-18, 2018.[5] Petitioner testified on July 17, 2018. Dr. Ring testified on behalf of respondent on July 18, 2018. After the hearing, petitioner filed an expert report by Dr. Marko Bodor, M.D.[6] and supporting medical literature. *See* Pet. Exs. 37-50. The parties submitted post-hearing briefs. Pet. Post-Hearing Brief (ECF No. 142); Resp. Post-Hearing Brief (ECF No. 146); Pet. Post-Hearing Reply (ECF No. 147).

This matter is now ripe for adjudication.

II. Finding of Fact

Prior to determining vaccine causation, there is one factual issue that must be resolved. The question is whether petitioner received the November 15, 2012 flu vaccine in her right shoulder or left shoulder.

A. Legal Standard

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records, which are required to be filed with the petition. §11(c)(2). The Federal Circuit has made clear that medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d at 1528. Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528.

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always

[5] This ruling only discusses entitlement and will only discuss evidence, including medical records, testimony and expert reports pertaining to petitioner's entitlement to compensation. Any evidence relevant to deciding damages will be discussed in a separate decision on damages.

[6] Dr. Marko Bodor is a licensed physician in the state of California. Pet. Ex. 51. He attended Harvard College for his undergraduate education and graduated in 1982. Dr. Bodor attended the University of Cincinnati for medical school. *Id.* Upon graduation in 1987, Dr. Bodor had a surgical internship at the University of California, San Diego and completed his residency in physical medicine and rehabilitation at the University of Michigan. *Id.* He has his board certification in Physical Medicine and Rehabilitation and sub-specialty board certifications in pain medicine and sports medicine. *Id.* Dr. Bodor is affiliated with the University of California, San Francisco Department of Neurological Studies and the University of California, Davis Department of Physical Medicine and Rehabilitation. *Id.* at 3. Additionally, Dr. Bodor is the founder of the Bodor Clinic, Interventional Spine and Sports Medicine, located in Napa, California. In this role, Dr. Bodor treats patients for neurological and orthopedic disorders. *Id.* at 3. Dr. Bodor is an adjunct assistant professor at the Touro University Osteopathic School and had held voluntary teaching positions at UCSF Medical School and at UC Davis. *Id.* at 6. Dr. Bodor has published numerous peer review articles and has been admitted as an expert in the Vaccine program before. Respondent did not object to petitioner submitting an expert report from Dr. Bodor in this case.

apply. In *Lowrie*, the special master wrote that "written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Lowrie*, at *19.

The Court of Federal Claims has recognized that "medical records may be incomplete or inaccurate." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998). The Court later outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Human Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery*, 42 Fed. Cl. at 391 (*citing Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such testimony must also be determined. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing § 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

B. Summary of Facts

1. Medical Records

On November 15, 2012, Jacinth M. Ruddock MD at the Jacobi Medical Center in New York City recorded that petitioner had presented for an "unscheduled med clinic encounter." The plan was "reestablishment of routine follow-up and health screening." The primary diagnosis was "routine general medical examination." The secondary/ chronic diagnosis is recorded as "lumbosacral spondylosis without myelopathy." Pet. Ex. 11. The same day, petitioner also had blood drawn for bloodwork and an EKG & Rhythm Strip Electrocardiogram. Pet. Ex. 35. The date on the record states that the blood was collected on November 15, 2012 at 16:24 and the results were completed the same day. *Id.* at 1. This record does not indicate from which arm petitioner had the blood drawn.

A further record from the same day, November 15, 2012, at 16:12 provides that Kumok Choi, RN, administered a flu vaccination to petitioner. The record provides that it was an intramuscular injection in "deltoid left." Pet. Ex. 1.

On December 14, 2012, petitioner was sworn in as a United States citizen at the United States District Court for the Southern District of New York. Pet. Ex. 17. Petitioner is a physician and was working as a medical researcher at Mount Sinai Hospital in New York. In January 2013 she returned to India to care for an aging and ill father.

The first medical record following petitioner's flu vaccination[7] is dated February 28, 2013. Pet. Ex. 3 at 1. It is handwritten, from the desk of Harsh Shah, M.D., a "specialist joint replacement surgeon" in Ahmedabad, India. *Id.* This record provides: "Dr. Kavita Desai, F/ 48, C/o pain – right shoulder – 3 months, H/o flu shot – followed by the [crossed out] 23rd November, Gradual onset → worsening, Previous treatment: nil." *Id.* A physical examination observed "bicipital tenderness, abduction/ internal rotation – painfully limited, painful arc +ue, neurologically (N)." Dr. Shah's assessment was an impingement syndrome. He advised Dolonex[8] once per day, supportive care, ultrasound, and follow up in fifteen days. Pet. Ex. 3 at 1.

On February 28, 2013, on Dr. Shah's referral, petitioner had an initial consult with Megha Sheth, a physical therapist at TH Institute of Physical Medicine in Ahmedabad. Pet. Ex. 12 at 1. The record provides: "[Petitioner] present[ed] with severe frozen shoulder/ adhesive capsulitis of right shoulder joint. [Petitioner] first received a flu shot intramuscularly on 15 Nov 2012. The IM injection site on right deltoid region started to hurt soon after injection on the same day. [Petitioner] assumed that the pain was due to flu vaccination and that it would go away after some time. Gradually, however, the Right shoulder started to become significantly painful, inflamed, stiff, restrictive and week. The patient is right-handed and right arm is her dominant arm." *Id.* The record also provides that petitioner was a "pediatrician, currently unable to work due to physical right shoulder and arm dysfunction." *Id.* In the "current condition," section of the record, it states, "Due to severe pain, stiffness, inflammation and weakness, it is excruciatingly painful and difficult for patient to move her right arm and perform day to day activities." *Id.* A physical exam revealed that petitioner had normal range of motion and strength with her left shoulder but had deficits in her right shoulder active range of motion. *Id.* at 3. The record for that visit noted that petitioner had an internal rotation of the right arm of only 28 degrees and external rotation of 25 degrees; her abduction was limited to 100 degrees and flexion limited to 110 degrees. *Id.* Petitioner was positive for Spurling's Test and the Empty Can Test on the right shoulder and negative on all special shoulder tests on the left shoulder. *Id.* It was recommended that petitioner begin physical therapy and recommended that she engaged in strength exercises, moist heat therapy to increase local circulation and decrease pain and inflammation; active and passive stretching to increase joint range of motion; peripheral joint mobilization/cryotherapy which is the application of cold to decrease local swelling and decease pain. *Id.* at 4.

Petitioner had physical therapy treatment at the Suresh Bramkumar Bhatt School of Physiotherapy (SBB College of Physiotherapy) from March 1, 2013 through Jul7 7, 2013. Pet.

[7] A record from Fracture and Orthopaedic Hospital in Ahmedabad, India dated January 4, 2013, lists petitioner, Dr. Kavita Desai, as the patient. It lists a "follow-up charge" of "600." Pet. Ex. 21 at 2.

[8] Dolonex is a non-steroidal anti-inflammatory.

Ex. 12. In April 2013, petitioner was not showing much improvement in her right shoulder. *Id.* at 29. She reported pain that was interrupting her ability to sleep. *Id.* She also explained she was taking high dose oral pain medication without much relief. *Id.* During therapy she was being treated with therapeutic exercises, manual stretching and cold treatments afterwards. *Id.* at 30.

There is a medical record from April 4, 2013 from G.M.E.R.S General Hospital in Gandhinagar, India for a 48-year old, "government employee," seeking treatment for right shoulder pain that has been ongoing for four months. Pet. Ex. 4 at 1. The medical record states, "Supervise for exercise in abduction of shoulder (illegible), concentrate to regain abduction and rotation." *Id.*

Petitioner returned to Dr. Shah on April 14, 2013. Pet. Ex. 3 at 2. Dr. Shah recorded, "One month of treatment of NSAIDS & exercises, no significant improvement." *Id.* He noted, "Abduction better, internal rotation—limited." *Id.* He advised an "Arthropatch"[9] daily for seven days, Tapnac-P[10] for ten days, rest and to follow-up in two weeks. *Id.*

On May 14, 2013, at a physical therapy appointment, petitioner reported severe inflammation, stiffness, pain and weakness of her right shoulder. Pet. Ex. 12 at 48. She also explained she began an oral corticosteroid regime for 10 days. *Id.* At a physical therapy appointment on May 16, 2013, petitioner reported that she could not perform proper activities or weight with her right arm and she was postponing her departure to the U.S. "due to this non-resolving, agonizing condition." *Id.* at 49. On May 30, 2013, petitioner had another physical therapy appointment where she reported that she did not benefit from oral corticosteroids and felt frustrated with her lack of progress and wanted to take a few days off. *Id.* at 57.

On July 17, 2013, petitioner returned to Jacobi Medical Center in New York. Pet. Ex. 2 at 35. The record explains that petitioner is "here with complaints of right painful shoulder. She reports that she received a flu shot last November in her right shoulder and has progressive pain and limited ROM." *Id.* The record states, "[Petitioner] has tried [physical therapy] in India without success. Benadryl has helped somewhat. Prednisone course in India has not. She is quite upset that Dr. Ruddock did not return any of her phone calls about this." *Id.* A physical exam was performed where petitioner demonstrated limited range of motion in active and passive movements in her right upper extremity, along with tenderness on right deltoid and anterior joint line. *Id.* at 36.

On July 26, 2013, petitioner had an appointment at the North Central Bronx Hospital with Dr. Steven Lager. Pet. Ex. 5. The history notes, "patient had flu injection into right deltoid in November 2012 and developed acute shoulder pain with capsulitis." *Id.* at 1. After a physical exam, where petitioner demonstrated decreased range of motion with her right shoulder, Dr. Lager diagnosed petitioner with "severe right shoulder capsulitis that did not respond to 4 months of PT in India." *Id.*

[9] Arthro patches are pain relief patches.

[10] Tapnac-P is Paracetamol, also known as acetaminophen.

Petitioner had a sports medicine appointment on August 8, 2013 with Dr. Darlene K. Jean-Pierre. Pet. Ex. 2 at 38. The clinic note states, "48 yF RHD referred to sports clinic for evaluation and treatment of R shoulder pain/stiffness s/p flu shot in 11/2012." *Id.* It was noted that petitioner had "diffuse tenderness to palpation" on her right upper extremity and she had a positive impingement sign. *Id.* Petitioner also demonstrated "some weakness with supraspinatus test." *Id.* Dr. Jean-Pierre diagnosed petitioner with adhesive capsulitis of shoulder and administered a subacromial/intraart injection. *Id.*

On August 12, 2013, petitioner had an occupational therapy shoulder evaluation. Pet. Ex. 2 at 42. It was reported that petitioner's diagnosis was "right shoulder adhesive capsulitis." *Id.* It was also noted that petitioner's dominate extremity was her "right." *Id.* The history of treatment stated, "…right shoulder pain since 11/2012 s/p flu shot, received aggressive PT in India (illegible) improvements, s/p injection subacromial region by sports on 8/8/2013." Petitioner reported that she had pain in her right shoulder in all directions at an 8/10. *Id.* She demonstrated limited range of motion in all directions. *Id.* at 43. Petitioner had her second occupational therapy appointment on August 16, 2013. *Id.* at 46. She reported "much improved pain" in the right shoulder, indicating that it was a 2/10 while at rest. *Id.* Petitioner had three other occupational therapy appointments in August 2013. *Id.* at 47-9. At the August 29, 2013 visit, petitioner reported that she was traveling for two weeks. *Id.* at 49. Petitioner returned to occupational therapy on October 4, 2013. *Id.* at 51. She reported reduced pain in her right shoulder and that she had been compliant with home treatments as much as possible. *Id.* She had another occupational therapy appointment on October 11, 2013. *Id.* at 52. At this appointment, she reported her pain as a 1/10. *Id.*

On December 26, 2013, petitioner had an appointment with Dr. Asha Shrestha at the Rheumatology Clinic at Jacobi Medical Center. Pet. Ex. 2 at 61. Petitioner explained that she was referred to rheumatology from the Sports Medicine Department for her right shoulder adhesive capsulitis. *Id.* Again, petitioner associated the onset with her right shoulder pain and dysfunction to her flu vaccination in November 2012. *Id.* Petitioner's history noted that petitioner received a steroid injection in August 2013 and physical therapy "recommended by rehab with some improvement now." *Id.* Petitioner also reported that she was not doing any additional occupational therapy, but had improvement in her right shoulder and reported, "right shoulder is better in terms of pain and [range of motion]. *Id.* During the physical exam, petitioner demonstrated limited range of motion, "mainly on internal rotation due to pain." *Id.* Dr. Shrestha diagnosed petitioner with right shoulder pain-suggestive of adhesive capsulitis-now improving," and she also stated that there was "no suspicion for connective tissue disease. *Id.* at 62. Dr. Shrestha recommended petitioner continue exercises occupational therapy taught her for the right shoulder and naproxen for pain as necessary. *Id.*

On April 10, 2014, petitioner had an appointment with Dr. Tony Wanich, an orthopedist. Pet. Ex. 6 at 1. In this record, it was noted that petitioner had right shoulder pain following the flu injection in 2013. *Id.* Petitioner reported her pain as a 4/10. *Id.* He performed a focused right shoulder exam, where petitioner demonstrated reduced range of motion on forward flexion, abduction, adduction and external rotation. *Id.* at 2. Petitioner had a positive Neer and Hawkin's test. *Id.* at 3. Dr. Wanich diagnosed petitioner with adhesive capsulitis and recommended she continue working with physical therapy. *Id.* at 4.

On April 15, 2014, petitioner presented to Performance Rehabilitation for an initial evaluation. Pet. Ex. 7 at 1. It was recorded that petitioner received a flu vaccination in November 2012 and that she developed frozen shoulder. *Id.* at 1. During the initial physical therapy evaluation, petitioner demonstrated reduced range of motion of her right shoulder on active movement. *Id.* Petitioner had a positive drop arm test, positive impingement test and positive Spurlings test. *Id.* Petitioner was assessed with right frozen shoulder with secondary bicipital tendinitis and some symptoms consistent with cervical radiculopathy. *Id.* Petitioner had physical therapy appointments at Performance Rehabilitation for the next six weeks. Pet. Ex. 7. At an appointment on May 13, 2014, petitioner reported that her shoulder was "getting better little at a time," and that her pain had been reduced. *Id.* at 18. On May 22, 2014, petitioner reported a "significant reduction in pain and improved [range of motion], strength and mobility," however, petitioner continued to report "difficulty and limitations in her ability to lift and reach overhead, behind her back and still has pain with activity." *Id.* at 22. She reported her pain at a 1/10 at best and a 5/10 at worst. *Id.* On June 4, 2014, at another physical therapy appointment, petitioner reported that "her shoulder is significantly better. She feels her range is a lot looser and is able to reach behind her back better." *Id.* at 28. Later in the month, on June 9, 2014, petitioner reported, "…significant range improvements day to day. Much easier reaching behind [her] back. Pain only with reaching across body." *Id.* at 32.

Petitioner had a follow-up appointment with Dr. Wanich on June 12, 2014. Pet. Ex. 8 at 1. In the history, he noted that petitioner "has demonstrated improvement with physical therapy." *Id.* After a physical exam of her right shoulder, he assessed petitioner with right shoulder adhesive capsulitis. *Id.* at 4. He wrote that petitioner had responded well to physical therapy, but "still lacks [internal rotation/external rotation]," and he gave her a new physical therapy referral. *Id.*

Petitioner travelled to India to again care for her ailing father and re-established care at the Suresh Bramkumar Bhatt School of Pysiotherapy, T.H. Institute of Physical Medicine in Ahmedabad, India. Pet. Ex. 13. At the initial evaluation on December 10, 2014, petitioner reported that after she received the flu vaccine in her right arm on November 12, 2012, she noticed pain which gradually increased as time progressed. *Id.* at 1. The history noted that petitioner had aggressive physical therapy from February to July 2013 in India and again in the U.S. *Id.* Petitioner reported that the pain was at worst a 3/10 and at rest a 0-1/10. *Id.* She reported mild limitation when trying to lift objects and mild to difficult when trying to reach overhead. *Id.* A physical examination of the shoulder revealed some limitation on external rotation and internal rotation, along with decreased strength (4/5) on the right shoulder compared to the left shoulder. *Id.* at 3. Physical Therapist Komal Patel assessed petitioner with, "Signs and symptoms are consistent with residual right frozen shoulder with bicipital tendinitis. Signs and symptoms are also consistent with cervical radiculopathy. *Id.* It was recommended petitioner engage in physical therapy for the right shoulder, including strengthening and stabilizing exercises, as well as, certain passive movements to improve range of motion. *Id.* Petitioner had physical therapy appointments from December 10, 2014 to April 28, 2017 in India. *See* Pet. Exs. 13, 18, 25.

These records demonstrate that petitioner's pain and range of motion ebbed and flowed but never fully resolved. For example, on January 12, 2016, petitioner reported "some improvement," and it was noted that, "[petitioner] is responding well to treatment and the prognosis is favorable." Pet. Ex. 13 at 34. On January 25, 2016, petitioner reported, "some improvement in range of motion, stiffness and pain today." *Id.* at 35. On May 31, 2016, petitioner reported that she still "has pain and is weak, but is able to reach [overhead] better with less difficulty." Pet. Ex. 18 at 32. Then on June 24, 2016, petitioner reported, "she fees better today. Reports some improvement in range of motion and pain." *Id.* at 40. She reported that her range of motion felt better, but was concerned about residual stiffness and weakness in her right shoulder joint on August 10, 2016. *Id.* at 55. Later in the month, on August 26, 2016, petitioner reported that she was "concerned about pain, weakness, stiffness and compromise in range of her right shoulder joint." *Id.* at 61. The assessment on that date states, "The patient is compliant and follows PT and treatment plan also at home. Symptoms of chronic immune mediated rotator cuff inflammation and tendinitis, subacromial bursitis and nerve damage." *Id.* On September 23, 2016, petitioner described a, "constant heavy, sore pain from inside out of her right shoulder joint." *Id.* at 72. She reported, "Pain is exacerbated by humid and cold weather. The weakness, residual stiffness and restriction of movement make her feel uncomfortable. She feels less than normal in her day to day activity." *Id.*

On September 29, 2016, petitioner had an MRI of her right shoulder at InFocus Diagnostics in Ahmedabad, India. Pet. Ex. 16. The MRI revealed a thin strip of fluid in the subacromial subdeltoid bursa with heterogeneous content and capsular thickening, mild effusion in the acromioclavicular joint with capsular fullness, degenerative signal changes in the antero-superior glenoid labrum and mild edematous changes in the rotator cuff interval space (mild changes of adhesive capsulitis). *Id.* The impression of the MRI was tendinosis involving anterior fibers of supraspinatus tendon, changes of subacromial subdeltoid bursitis and mild effusion involving AC joint with capsular fullness. *Id.*

Petitioner had an appointment with Dr. Parag Shah on October 3, 2016. Pet. Ex. 22 at 1. He noted that petitioner had a history of right shoulder pain for four years. *Id.* He wrote, "No fall/trauma, H/O flu vaccine 4 years ago, followed by severe pain, [illegible], reduced range of motion…mild impingement…" *Id.* He recommended petitioner continue regular strengthening and continue to use cold/hot packs. *Id.*

On October 11, 2016, petitioner had another physical therapy appointment. Pet. Ex. 25 at 1. She explained that, "As soon as the treatment is suspended, the pain, stiffness, weakness and restriction in movement reappears." *Id.* Petitioner continued physical therapy treatment and had multiple appointments through April 28, 2017. *See* Pet. Ex. 25. Again, her progress in regaining full movement and reducing the pain in her right shoulder appeared to wax and wane. For example, on November 29, 2016, petitioner reported that, "She is getting more motion and less pain since her last visit," but then on December 6, 2016, petitioner reported her shoulder, "…feels stiff since her las visit. There is also pain on extended ranges of movements." *Id.* at 12, 15. On February 16, 2017, petitioner reported painful range of motion reaching overhead and behind her back, but later in the month, on February 21, 2017, she reported a reduction in pain. *Id.* at 29, 30. On April 11, 2017, petitioner reported pain and difficulty sleeping throughout the night and soreness in the right shoulder joint. *Id.* at 42. It was noted that her passive flexion was

within normal limits and passive external rotation was also within normal limits, but with moderate pain. *Id.* By April 20, 2017, petitioner was reporting improvement in ranges of movement, but mild sleep discomfort continued. *Id.* at 45. On April 28, 2017, petitioner reported that she had been doing her exercises at home, felt a reduction in pain, and her sleep disturbances had improved. *Id.* at 47.

After returning to the U.S., petitioner sought treatment from Dr. Gregory Difelice, a trauma surgeon at Orthopaedic Surgery, Sports Traumatology & Joint Reconstruction. Pet. Ex. 27. In petitioner's history, it was noted that she was right hand dominant who has had right shoulder pain and stiffness "for several years after receiving the flu shot." *Id.* at 1. Dr. Difelice performed a focused physical exam of the right shoulder which showed active forward flexion 1-160 degrees, abduction was 1-160 degrees, external rotation was 0-60 degrees and active internal rotation to T12, all with good kinematics. Petitioner's strength was 5/5 in the plane of the scapula; 5-/5 in external rotation; and 5-/5 in subscapula. *Id.* at 2. She had a negative Spurling's test, but positive impingement signs. *Id.* Dr. Difelice diagnosed petitioner with chronic rotator cuff syndrome, possibly related to flu shot. *Id.* He recommended petitioner continue at home exercises, ice and over-the-counter NSAIDs and Tylenol as needed for pain control. *Id.*

On May 21, 2018, petitioner had an appointment with Dr. Lori Ciuffo for a follow-up. Pet. Ex. 33 at 1. It was noted in her history that petitioner had "right adhesive capsulitis from flu injection who presents for routine care." *Id.* at 1. The physical exam revealed right shoulder range of motion was limited by pain. *Id.* at 2. At this appointment, petitioner declined additional vaccinations, but was given a referral for physical therapy. *Id.* at 2. Petitioner was diagnosed with right shoulder adhesive capsulitis. *Id.* at 4. Petitioner indicated that she did not feel like her shoulder was improving and did not want to return to rehab. *Id.*

2. Petitioner's Affidavits

Petitioner also submitted three affidavits. Pet. 1st Affidavit, signed August 29, 2014; Pet. 2nd Affidavit, signed October 14, 2014; Pet. 3rd Affidavit, signed April 17, 2018. They generally address the shoulder injury's impact on her life and the treatment she sought beginning on February 28, 2013.

In her first affidavit, petitioner stated that the November 12, 2012 flu vaccination "was administered in my right upper arm." Pet. 1st Affidavit, ¶ 5. "Later that day my right arm and shoulder started hurting." Id. "I assumed that my shoulder was sore because of the flu vaccination and that it would resolve over time. However, the pain did not go away and the right shoulder became increasingly painful, stiff, inflamed, and weak." Id. at ¶ 6.

In her second affidavit, petitioner provided: "While I developed severely painful, inflamed, restrictive and weak right shoulder joint and arm following [the flu vaccination] given to me on 15NOV2012 in my right upper arm, I was in India from February 2013 to July 2013." Pet. 2nd Affidavit, ¶ 2. "Once I reached India, immediately, I sought consultation of Dr. Harsh Shah there on 28FEB2013 – who is a noted orthopedist specialized [sic?] in joint conditions and surgery – for the reaction I was experiencing following Flu vaccination in my right shoulder joint and arm[.]" Id. at ¶ 3.

In petitioner's third affidavit, she stated that she received the flu vaccine injection on November 12, 2012, in the right, upper arm. Pet. 3rd Affidavit, ¶ 1. She stated that, "on the same day, my right shoulder and arm started hurting. There was pain, some swelling, heaviness and tenderness at and around the injection site." *Id.* at ¶ 2. She also stated that she experienced flu like symptoms approximately 8 to 10 days after receiving the flu vaccine on November 15, 2012. *Id.* at ¶ 9. She stated that in the VAERS report, filed on July 24, 2013, petitioner mentioned this event. *Id.* at ¶ 10. Petitioner stated that, "By the time I reached my home city in India on February 13, 2013, my right shoulder and arm SIRVA had worsened a great deal. The pain, stiffness, and tenderness of right shoulder and upper arm was agonizing." *Id.* at ¶ 12. Petitioner also clarified that when she met with Dr. Harsh Shah on February 28, 2013, she told him that she began to have flu-like symptoms around her birthday, of November 23, which is why he noted, "flu + S 23rd November." *Id.* at ¶ 14. She stated that she opted for home remedies to treat for the flu symptoms, like lemon juice, plenty of water, occasional regular strength Tylenol for fever and body ache and applied Tiger Balm on her forehead for headache. *Id.* at ¶ 14.

3. Petitioner's Testimony

During the hearing, petitioner testified that on November 15, 2012, when she lived in New York City, she had an appointment with Dr. Ruddock for a routine checkup. Tr. 21. She testified that she saw Dr. Ruddock at 3:49 pm and had an ECG at 4:08 pm the same day. Tr. 22. Petitioner explained that Nurse Wanda Cruz was the person who administered the ECG. After the ECG, petitioner stated, that Dr. Ruddock wanted petitioner to get her blood work. *Id.* at 23. Petitioner testified that in order to get her blood drawn, she had to walk down a long corridor to a room where the blood work was performed by two technicians. *Id.* at 24. She stated that one of the technicians attempted to locate a good vein in her armpits, but they could not find a prominent vein. *Id.* Petitioner testified, "So they first tried it on my right arm but they couldn't get a proper vein because there was significant tests and they needed like two, three tubes of blood. So then they tried on my left arm and they were able to…find a deep vein from where they could take the blood." *Id.* at 24. Petitioner also reviewed the blood work medical record and verified that the record states that the blood was drawn at 4:24 pm. *Id.*

After the blood was drawn, petitioner walked back to the nurses' station to receive her flu vaccine. Tr. 32. Petitioner explained that the nurse administering the vaccination noticed the tape on petitioner's left arm from the blood work and indicated that she would administer the vaccine on the right arm. *Id.* Petitioner testified that the flu shot came after she received her blood work, even though the time stamp on the vaccine administration record indicates the vaccine was given at 4:12 pm. Tr. 33. Petitioner explained that the ECG was administered at 4:08 pm and it took at least ten minutes. Tr. 34. Therefore, she could not have received the vaccination during the course of the ECG, at 4:12 pm. *Id.*

Petitioner further testified that the person who administered the shot was a tall, Hispanic woman. Tr. 35. She explained that it was likely the same nurse that administered petitioner's ECG, Nurse Wanda Cruz. Tr. 35, 165-66. Petitioner explained that when she examined the vaccination record, which indicated Registered Nurse Kumok Choi administered the vaccine, she knew it was wrong. Tr. 36. She testified that when she went back to Jacobi Medical Center to

request her vaccination record, she spoke to the nursing supervisor to report two discrepancies in her medical record. Tr. 37. Petitioner stated that the nursing supervisor told her that often the nurse administering the vaccination is someone different than the person who enters the record. *Id.* The same day petitioner went to retrieve her vaccination record, she met with Nurse Kumok Choi and described her as an "a short, slim, purely Asian female," and, "she had no recollection of me." Tr. 164.

Petitioner testified that after she left Dr. Ruddock's office on the afternoon of November 15, 2012, "as soon as I reached home there was significant pain on my right shoulder." Tr. 49. She stated that she thought that the pain would subside, but as the evening progressed petitioner "felt a lot of heaviness and pain-which wasn't normal for other injections." *Id.* She applied ice on her right shoulder and took pain medication to soothe the pain. *Id.* Petitioner stated that the pain continued through the next day, but she thought it would go away, as some shots are more painful than others. *Id.* She testified that the pain would not cease. *Id.* By mid-December, she could not move her right arm all the way up when she went to take a shower. Tr. 49-50. She stated that slowly she could not comb her hair on the right side or put her arm in the right sleeve of her jacket. Tr. 50.

During cross-examination, petitioner explained that she had "considerable pain on the day of the vaccine, but it gradually became worse and then the stiffness and movement restrictions started happening. Tr. 225. Petitioner testified that the pain in her right shoulder began immediately, but she thought it was going to go away. Tr. 171-72.

In late January she left for India and experiencing a lot of pain in her right shoulder. Tr. 50. She stated that once she reached India, she contacted Dr. Shah because her arm was "freezing." *Id.* She testified that between November 15, 2012, the day of the vaccination, and her first appointment with Dr. Shah on February 28, 2014, her right shoulder condition did not improve. Tr. 51. She stated that instead, her arm was getting progressively stiffer. *Id.* Petitioner stated that she was unable to perform day to day personal activities because she is right hand dominant. *Id.* She explained that even when she was at rest, she was feeling pain and her day-to-day activities were getting limited. Tr. 54.

Petitioner explained that when she went to India to care for her father, she met with Dr. Harsh Shah on February 28, 2013. Tr. 38. She testified that she recounted what had occurred regarding her shoulder to Dr. Shah and attributed the pain to the flu vaccine she received on November 15, 2012. *Id.* However, he recorded that petitioner received the flu vaccine on, "15 Nov. 2015," which was an obvious error in recording the date, as it had yet to happen. Tr. 39. She testified that other than the date of vaccine administration, the history was correctly recorded by Dr. Shah. *Id.* Petitioner testified that Dr. Shah gave her a referral for physical therapy. Tr. 47.

Petitioner testified that the treating orthopedist in India told her to go to physical therapy every day because he did not want her shoulder to become completely frozen. Tr. 56. She was also prescribed a high dose painkiller. *Id.* Petitioner testified that during physical therapy she would perform arm movements, stretches and they would use ultrasound and hot packs on her right shoulder. *Id.* Petitioner testified that even by June 2013, after two months of physical

therapy, she could only raise her arm about 70 degrees and she still could not comb her hair with her right hand. Tr. 68.

Petitioner returned to the U.S. from Indian in the first week of July 2013. Tr. 72. She described her right should as "very bad." Petitioner testified that she filed the first VAERS report on July 24, 2013. Tr. 40. She stated that in the first VAERS report she indicated that she had a lot of pain at the injection site immediately after the IM [intramuscular] flu shot in the upper arm. *Id.* The VAERS report read that developed a severe flu-like syndrome with a low-grade fever that lasted for two weeks. *Id.*; Pet. Ex. 10 at 3. Additionally, the VAERS report described the condition of her right shoulder after receiving the flu vaccine as, "Gradual development of intense pain in right shoulder and arm and restriction of movements of right arm and shoulder akin to frozen shoulder from 11/15/2012 until 7/24/2013." *Id.* Petitioner testified that she filed a follow-up VAERS report on August 14, 2014. Tr. 42; Pet. Ex. 10 at 3. She testified that she did not learn about the Vaccine Injury Compensation Program ("VICP") until later, during a follow-up call with the CDC. Tr. 43.

Petitioner explained that she had a gap in treatment of a few months due to a lapse in health insurance. Tr. 75. She saw Dr. Tony Wanich at Montefiore Medical Center in New York City for the first time in April 2014. Pet. Ex. 6. He recommended she begin physical therapy again. *Id.* Petitioner testified that by the third day of physical therapy at Performance Rehabilitation, she "felt a bit loose and….more improvement." Tr. 76. She stated that during physical therapy, she was doing exercises which required more effort gradually to extend her range of motion. Tr. 81. Petitioner engaged in physical therapy in the U.S. from April 2014 to November 2014. Tr. 74.

In December 2014, petitioner returned to India to care for her father. Tr. 45. She resumed physical therapy in India. Pet. Ex. 13; Tr. 90. She described that her arm felt "heavy," and she experienced pain and stiffness in January 2015. Tr. 90. She explained that after about five months of physical therapy, her shoulder, "in general was getting better." Tr. 92. She stated that if she attempted to lift heavy groceries or boxes, she exacerbated the pain in her shoulder Tr. 95. Petitioner testified that during the dry and warm seasons, she was getting better, but would experience the heaviness and a lot of pain if she overworked or overstretched her arm. *Id.* She stated that in 2015, compared to 2013, the degree of pain had decreased and stopped taking pain medication daily in 2015. Tr. 96.

By the fall of 2016, petitioner explained that her right shoulder "had definitely improved, but it was not normal." Tr. 112. She stated that by October 2016, she was getting some relief in her right shoulder with the variety of treatments she was undergoing at the time, but the relief was temporary. Tr. 114. She testified that during the monsoon season in India (July through mid-October, where the weather is, "very, very damp," she had a "tough time with her right shoulder." Tr. 114, 119-20.

Petitioner testified that in winter 2017, the time between physical therapy appointments decreased. Tr. 115. But she felt that when the weather was very wet or really cold, she would experience a lot of pain and dysfunction in her right shoulder. *Id.* However, despite these "spells when bad weather," occurred, she felt better and improvement with her overall ranges of

motions. *Id.* She stated that in April 2017, she had felt much better, but still not 100 percent. Tr. 116. Her sleep disturbances decreased and she was not consistently using any pain medication. Tr. 117-18.

By August 2017, petitioner stated that she had a dull, continuous aching pain and some sleep disturbances, but that were "not as severe as in 2013 or 2014." Tr. 120. She felt she reached a plateau of residual problems and needed a break from physical therapy. *Id.* In December 2017, she was "feeling much better," but still experienced some pain reaching behind her back and overhead, which she considered "normal." *Id.*

Petitioner testified that "some background pain is always there." Tr. 121. She explained that "during good seasons, when I don't overstretch or overwork [her] arm," she feels good about her movements, sleep and activities. Tr. 121. But during the monsoon season or colder months, her pain would come back. *Id.* She testified that by March 2018, she reported to her physical therapist that she had pain in her right shoulder, but had improvement in movement since the wintertime. Tr. 124. She stated that since March 2018, her shoulder issues had remained stable and she had been feeling much more comfortable sleeping and in her movements. Tr. 125.

Petitioner described a variety of activities that can aggravate her right shoulder, including vacuuming, carrying more than six pounds in her right hand, or carrying a large bag. Tr. 130-31. She stated that she purchased a specialized cart to assist her with grocery shopping. Tr. 133. During the hearing, petitioner demonstrated her range of motion in her right shoulder. Tr. 136. During the hearing, she was able raise her left arm about 180 degrees (normal)but her right arm only to 150 degrees. *Id.* When asked about reaching behind her back, she was able to get to about the T-5 level (normal) with the left arm but only to the T-12 level with the right. Tr 135. She testified that all of the treating physicians she has seen for her right shoulder told her she would experience residual problems with her right shoulder forever. Tr. 146.

C. Site of Vaccine Administration: Left Arm/Right Arm

Petitioner asserted that she received the covered flu vaccine in her right arm on November 15, 2012. Pet. Aff. at 1; Petition at ¶ 3. Respondent argued that the vaccination record documents the site of administration of petitioner's vaccine in the left upper arm. Resp. Rept. at 9. Respondent stated in his post-hearing brief, "The vaccination record documents the site of administration of petitioner's influenza vaccine as the left deltoid. Pet. Ex. 1 at 1. Subsequent medical records that reflect petitioner's receipt of the vaccination in the right shoulder are based on petitioner's statements to the providers and not on independent information." Resp. Post-Hearing Brief at 16.

Medical records may be outweighed by testimony that is given later in time that is "consistent, clear and cogent, and compelling." *Camery,* 42 Fed. Cl. At 391 (*citing Blutstein v. Sec'y of Health & Human Servs.,* No. 90-2808, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). In cases in which a court has based a finding upon lay testimony, there must be corroborating evidence, either medical or otherwise to support the claim. *Epstein v. Sec'y of Health and Human Servs,* 35 Fed. Cl. 467, 478 (1996).

In this case, petitioner has provided consistent, clear and cogent and compelling testimony, which is corroborated by medical records, to demonstrate that she received the flu vaccination on November 15, 2012 in her right arm. Petitioner explained that the vaccine was administered in her right arm because the blood work she received the same day, had been performed on her left arm. Pet. Ex. 35; Tr. 24.

Additionally, petitioner's testimony about when she received the flu vaccination at the medical appointment on November 15, 2012, also demonstrated that there was an error in vaccination record. The vaccination record indicated that she received the flu vaccine at 4:12 pm EST. Pet. Ex. 1 at 1. However, this time stamp is inconsistent with both petitioner's testimony about the timing of the procedures she had performed at the medical appointment on November 15, 2012 and with the time stamp on the medical records for her EKG.

The medical appointment record from November 15, 2012 indicates that she met with Dr. Ruddock at 3:49 pm. Pet. Ex. 11. She also had an EKG & Rhythm Strip Electrocardiogram the same day and that it is documented to have taken place at 4:08 pm. Pet. Ex. 35. Petitioner testified that this type of procedure took approximately 10 minutes to perform this test. Tr. 34. She explained that after the EKG, she went to another part of the office to have her bloodwork drawn. Tr. 27. The record indicates that she had her blood drawn at 4:24 pm. Pet. Ex. 35. Petitioner testified that after the blood work specimen was collected, she went back to the front nursing station of the office to collect her paper work and receive the flu vaccine. Tr. 32. Petitioner testified that even though the vaccine record indicates she was administered the vaccine at 4:12 pm, this could not have been the case, because that would have during her EKG procedure. Tr. 32-4.

On February 28, 2013, at the appointment with Dr. Shah, petitioner asserted that she received the flu vaccination in her right arm. Pet. Ex. 3 at 1. Petitioner consistently reported that she received the flu vaccine on her right arm to all her other treating physicians. *See* Pet. Exs. 2, 3, 5 and 29.

Petitioner testified clearly and credibly that she received the vaccination in her right arm. Additionally, the medical records, particularly the medical records from the date she received the vaccination, corroborates her testimony with respect to the order of procedures performed the same day but contains other errors regarding timing of the procedure as described above. The nursing supervisor told the petitioner that the person making the chart entry is different than the one administering the shot and indeed it appeared that that was the case in this situation. Thus, it seems likely that the entry of left arm was made in the chart as the most frequent location but without Nurse Choi having seen the actual administration of the vaccine in this case. Therefore, the undersigned finds that petitioner received the November 15, 2012 flu vaccination in her right arm.

III. Ruling on Entitlement

A. Legal Standard for Entitlement

The Vaccine Act provides two avenues for petitioners to receive compensation. The petitioner may demonstrate either that she suffered a "Table" injury, or that she suffered a different injury which was caused-in-fact by a vaccine listed on the Vaccine Injury Table. §§ 3000aa-13(a)(1)(A), 11(c)(1); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner's claim predates the inclusion of SIRVA on the Table, she must prove her claim by showing that her injury was caused-in-fact by the vaccination in question. §300aa-11(c)(1)(C)(ii). To do so, petitioner must establish, by preponderant evidence: "(1)" a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires petitioners to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.,* 219 F.3d 1357, 1361 (Fed. Cir. 2000). Expert testimony in the Vaccine Program is usually evaluated according to the factors set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993); *see also Cedillo,* 617 F.3d at 1339 (citing *Terran v. Sec'y of Health & Human Servs.,* 195 F.3d 1302, 1316 (Fed. Cir. 1999). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. v. Sec'y of Health & Human Servs.,* 592 F. 3d. 1315, 1324 (Fed. Cir. 2010). The *Daubert* factors are used in *weighing* the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.,* 94 Fed. Cl. 53, 66-67 (2010).

Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1362 (Fed. Cir. 2000)). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder Ex Rel. v. Sec'y of Health & Human Servs.,* 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner,* 522 U.S. 146 (1997)). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly,* 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

B. *Althen* Prong One

Under *Althen* prong one, the petitioner must present a theory explaining how the relevant vaccine can cause the petitioner's injury. *Althen*, 418 F.3d at 1278. In this case, the petitioner's theory of causation is SIRVA. The Federal Circuit has held that recognition of a link between vaccine and injury on the Vaccine Injury Table supports petitioner's burden under *Althen* prong

one. *Doe 21 v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds,* 527 Fed. Appx. 875 (Fed. Cir. 2013).

1. Respondent's Expert's Opinion to *Althen* prong one

In his written report, Dr. Ring wrote that petitioner was correctly diagnosed with adhesive capsulitis and "the condition evolved as expected." Resp. Ex. A at 3. He explained that adhesive capsulitis causes painful stiffness. *Id.* at 2. Dr. Ring wrote that, "Adhesive capsulitis is an extremely common, idiopathic, temporary stiffness of the glenohumeral joint….Adhesive capsulitis resolves over time, and there are no interventions that clearly alter the natural history." *Id.* He stated that, "most people do stretching exercises and use occupational non-opioid pain relievers until the problem resolves. This is consistent with the treatment that was sought by [petitioner] in India from February 29, 2013 through July 7, 2013, and in the US from April through June of 2014." *Id.*

Dr. Ring stated that because the shoulder is a common site of vaccine administration and prevalence of adhesive capsulitis, "the two are likely to be linked temporally, on occasion." *Id.* He acknowledged that prior to being hired by respondent for this case he had never heard of SIRVA and did not recall treating any patients complaining of chronic shoulder pain after vaccination. Tr 281. Dr. Ring opined that the needle used for vaccination is too short to enter the subacromial space and that a spinal needed is necessary for subacromial injections. *Id.*

Dr. Ring stated that, "As is typical for adhesive capsulitis, her condition resolved with few deficits (last documented shoulder forward elevation of 160 degrees, which is within range of normal). Any ongoing shoulder pain is more likely than not related to typical age-related changes in the rotator cuff. *Id.* at 3. He observed that in 2017, petitioner was in the care of Dr. Gregory DiFelice, a "nationally renowned shoulder surgeon at the prominent and well-respected Hospital for Special Surgery in New York," and he assessed petitioner with rotator cuff tendinosis. *Id.* at 4. Dr. Ring stated that, "it is clear from Dr. DiFelice's notes that the adhesive capsulitis resolved, and any residual symptoms are due to another: age-appropriate changes in the rotator cuff tendons." *Id.*

During the hearing, Dr. Ring explained that adhesive capsulitis cannot cause rotator cuff syndrome. Tr. 258. He also stated that rotator cuff syndrome cannot be a sequala of adhesive capsulitis. *Id.* He testified that he agreed with Dr. DiFelice's assessment from the August 8, 2013 visit that petitioner had adhesive capsulitis. Tr. 264. He stated that the record indicated there was a restriction of motion and "idiopathic stiffness of the shoulder," which was consistent with adhesive capsulitis. *Id.*

Dr. Ring stated that typical treatment for adhesive capsulitis is physical therapy that includes stretching exercises. Tr. 265. He explained that some people may experience slight stiffness at the end of treatment, but found that there was no evidence in petitioner's case of residual stiffness associated with her adhesive capsulitis. Tr. 265-66. He testified that petitioner's final motion, "is somewhere between 160 and 180 degrees, all of which are within normal limits." Tr. 266. He noted that on May 5, 2018, at petitioner's second visit with Dr. DiFelice, petitioner was diagnosed with rotator cuff syndrome of the right shoulder, which is a

separate and different problem that she presented with in 2013. Tr. 266-67. Dr. Ring testified that at the visit in 2018 with Dr. DiFelice, petitioner was not exhibiting any stiffness, but instead describing pain and she had an MRI showing rotator cuff tendinosis, which is "clearly a different problem" from the pain caused by her adhesive capsulitis that she presented with in 2013. Tr. 267. He opined that the pain she was describing when testifying was the result of her rotator cuff tendonitis and not from the pain she experienced after receiving the flu vaccination in November 2012. Tr. 267.

Dr. Ring also testified that there is no evidence that petitioner's adhesive capsulitis was caused by the flu vaccine injected into her right shoulder. Tr. 268. He stated that adhesive capsulitis was extremely common and idiopathic, so "there is no known cause." *Id.* When asked if it was possible for a person to experience an inflammatory response to a vaccination as a proposed mechanism for causing adhesive capsulitis, Dr. Ring responded, "No, it doesn't make any sense to me." Tr. 268. He conceded that an injection in the deltoid can cause a local inflammatory response but reiterated that it cannot cause adhesive capsulitis. Tr. 269. Dr. Ring also opined whether the needle for a vaccination would be long enough to cause a physical injury and he stated that it is too short to get into the shoulder joint or subacromial space. *Id.* He stated that that in order to give an injection into the subacromial space, a spinal needle is used, which is three or four inches long. *Id.* He stated that he does not think that the influenza vaccine causes adhesive capsulitis or rotator cuff tendinopathy. Tr. 270.

Dr. Ring stated that the article by Atanasoff et al.,[11] which describes shoulder injuries related to vaccine administration, showed that people had "coincident shoulder site immunization and shoulder soreness." Tr. 273. He testified that many of the subjects described in the Atanasoff article had rotator cuff tendinopathy or adhesive capsulitis. *Id.* Dr. Ring opined that "a causal association made where only a temporal association was observed." *Id.*

After reading the Vaccine Injury Table's definition of SIRVA, Dr. Ring conclude that petitioner did not meet the definition because "adhesive capsulitis" could explain her shoulder symptomology. Tr. 279. Dr. Ring concluded that he could not link petitioner's rotator cuff syndrome to her diagnosed adhesive capsulitis or to the administration of the flu vaccine in November 2015. *Id.*

2. Petitioner's Expert's Opinion to *Althen Prong One*

Petitioner submitted an expert report from Dr. Marko Bodor post-hearing. Pet. Ex. 37. In his report, Dr. Bodor explained, "in the weeks and months following her flu vaccination, [petitioner] developed adhesive capsulitis. I have found adhesive capsulitis (frozen shoulder) to be clearly documented in 56% (9/16) of SIRVA claimants whose medical histories I have reviewed in the last few years. This is much higher than the 3-5% lifetime risk of frozen shoulder in the general population." Pet. Ex. 37 at 3.

[11] Atanasoff, S., et. al., *Shoulder injury related to vaccine administration (SIRVA),* 28 Vaccine 8049-8052 (2010). [Resp. Ex. A2; Pet. Ex. 39].

Dr. Bodor explained that the article[12] he co-authored, which was the first to describe "vaccination-related shoulder dysfunction," hypothesized that a vaccine injected into the subdeltoid bursa caused a periarticular inflammatory response, subacromial bursitis, bicipital tendonitis and adhesive capsulitis. Pet. Ex. 38. He explained that he studied the length and type of needles used in vaccinations and the distance between the skin and subdeltoid bursa using ultrasound to determine whether the vaccination could penetrate the subdeltoid bursa. *Id.* He found that in individuals with a body mass index ("BMI") between 19 and 31, the distance between the skin and the subdeltoid bursa range from 8 to 16 mm in the upper third of the deltoid muscle. Id. He found that in 21 normal health adults, a 25.4 mm (one inch) vaccination needle inserted to 75% of its length in the upper part of the deltoid could penetrate the bursa in all subjects; and if inserted to 50% of its length, it would still penetrate the bursa in most subjects. Pet. Ex. 37 at 1.

Dr. Bodor stated that Dr. Ring's belief that a 100 mm spinal needle is necessary to reach the subacromial bursa, is not surprising, as Dr. Ring did not appear to review the article Dr. Bodor co-authored discussing ultrasound measurements of the distance between the skin and the subdeltoid bursa. Pet. Ex. 37 at 1. The ultrasound measurements have allowed more precise measurements of the shoulder structure, including the skin, fat, deltoid muscle, infraspinatus tendon and the bone of the humeral head. *Id.* at 2. Dr. Bodor agreed that the 100 mm spinal needle is used on rare occasions to reach the subacromial bursa. Pet. Ex. 37 at 2. He explained that one would have to use the longer needle to reach the subacromial bursa under the acromion when the needle comes from the side rather than the top of the shoulder because the distance to the target is longer. Pet. Ex. 37 at 2. He indicated that you can use a much shorter needle and direct approach to reaching the subdeltoid bursa. *Id.*

Dr. Bodor wrote that it was his opinion that, "vaccination needles can reach the subdeltoid bursa, rotator cuff and bone below the rotator cuff and cause acute injuries and chronic pain on the basis of deposition of antigens and a persistent inflammatory response." *Id.* at 3.

He explained that petitioner's height and weight placed her at a higher risk for overpenetration of a vaccination needle, if provided in the upper third of the deltoid muscle, "the location of the subdeltoid bursa and rotator cuff." *Id.* at 3. He observed that petitioner is 5'2" tall and weighed 119 pounds on October 4, 2012. Her BMI was 22, at the lower end of their 19-31 test range. He therefore estimated that the distance from skin to the subdeltoid burse was in the range of 6-10 mm or well within the range of a standard vaccination needle. He opined that the vaccine was likely injected into petitioner's subdeltoid bursa and adjacent rotator cuff, causing immediate pain and an inflammatory response. *Id.*

3. Petitioner has demonstrated *Althen* prong one by preponderant evidence.

As noted above, the respondent has added SIRVA after the receipt of an intramuscularly administered seasonal flu vaccine to the Vaccine Injury Table. When proposing the addition of SIRVA to the Vaccine Table, respondent discussed the mechanism by which this injury is caused. *See* National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury

[12] Bodor, M., & Montalvo, E., *Vaccination-related shoulder dysfunction*, 25 Vaccine 585-587 (2007). [Pet. Ex. 38].

Table, 80 Fed. Reg. 45132, 45137 (July 29, 2015). The undersigned takes judicial notice of this fact and such recognition of the causal association between vaccine and injury has been held to support the establishment of the theory required by the first *Althen* prong. *See Doe 21 v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 178, 193 (2009), *rev'd on other grounds,* 527 F. App'x 875 (Fed. Cir. 2013).

Further, petitioner's expert, Dr. Bodor, provided a sound and reliable medical theory of causation which is supported by the medical literature. He opined that the direct injection into the bursa by the vaccination stimulated an inflammatory response which eventually led to adhesive capsulitis. Pet. Ex. 37 at 3. This theory is supported by the medical literature filed by petitioner. Specifically, Dr. Bodor referenced the Atanasoff article which explained, "If…a vaccine is inadvertently injected into the synovial space of the shoulder (bursa or joint), pre-existing antibody in the synovial tissues, present as a result of earlier naturally occurring infection or vaccination, may lead to a more prolonged inflammatory response." Pet. Ex. 39 at 3. Further, the Atanasoff article stated,

> Although shoulder dysfunction due to mechanical or overuse injury is always a diagnostic consideration, the rapid onset of pain with limited range of motion following vaccination in our series of patients is consistent with a robust and prolonged immune response within already-sensitized shoulder structures following injection of antigenic substance into the subacromial bursa or the area around the rotator cuff tendon. We believe that this type of phenomenon is not due to a specific vaccine, but results from injection of a vaccine antigen to which a person has previously been sensitized as a result of previous naturally occurring infection or past vaccination.

Pet. Ex. 39 at 3.

While Dr. Ring asserted that a much larger needle is needed to reach the subacromial bursa space, the Atanasoff article also confirmed that over penetration by a standard needle used for vaccination could reach the bursa, particularly in patients with lower BMIs. Pet. Ex. 39 at 3. Further, the Atanasoff article indicated that individuals may have pre-existing shoulder conditions, like impingement syndrome or adhesive capsulitis, but have no symptoms or dysfunction until provoked by vaccination-associated synovial inflammation. *Id.*

While this case was Dr. Ring's first exposure to SIRVA, Dr. Bodor has done considerable research on the subject and demonstrated significant knowledge of the specific anatomy involved in SIRVA injuries and the potential for a standard vaccine needle to reach the underlying structures when the shot is administered in the top third of the deltoid. I found his opinion to be more persuasive.

Additionally, the Vaccine Program has a well-established track record of awards of compensation for SIRVA being made on a cause-in-fact basis in this program. *See, e.g., Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664V, 2018 WL 3083140 (Fed. Cl. Spec. Mstr. Mar. 30, 2018) (rev. den., 142 Fed. Cl. 329 (2019)); *Loeding v. Sec'y of Health & Human Servs.*, No. 15-740V, 2015 WL 7253760 (Fed. Cl. Spec. Mstr. Oct. 15, 2015) (noting that "respondent 'has concluded that petitioner's injury is consistent with SIRVA; that a

preponderance of evidence establishes that her SIRVA was caused in fact by the flu vaccination she received on October 14, 2014; and that no other causes for petitioner's SIRVA were identified."); *Johnson v. Sec'y of Health & Human Servs.*, No. 16-165V, 2016 WL 3092002 (Fed. Cl. Spec. Mstr. Apr. 13, 2016) (awarding compensation for a SIRVA caused-in-fact by the influenza vaccine).

Therefore, the undersigned finds petitioner has provided by preponderant evidence that the flu vaccine administered intramuscularly can cause SIRVA and satisfied the first *Althen* prong.

C. *Althen* Prong Two

Under *Althen* prong two, petitioner must demonstrate a logical sequence of cause and effect showing that the vaccination was the reason for her injury. The second prong focuses on specific causation, whether the administered vaccine *did* cause the injury. *Pafford v. Sec'y of Health & Human Serv.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006). This distinction "has been described as the 'can cause' vs. 'did cause' distinction." *Stapleford v. Sec'y of Health & Human Servs.*, No. 03-234V, 2009 WL 1456441 at *18 (Fed. Cl. Spec. Mstr. May 1, 2009).

Although petitioner's claim does not constitute a Table injury, the QAI criteria for SIRVA has been found to be persuasive regarding the factors necessary to demonstrate a logical sequence of cause and effect. *Tenneson v. Sec'y of Health & Human Servs.*, No. 16-1664, 2018 WL 3083140 at *7 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *aff'd,* 142 Fed. Cl. 329 (2019); *Forman-Franco v. Sec'y of Health & Human Servs.,* No. 15-1479, 2019 WL 7602582 at *9.

The QAI provides that a "vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following,"

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings and/or diagnostic studies occurring after vaccine injection;
(ii) Pain occurs within the specified time period;
(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. Part 100.3(c)(Qualifications and Aids to Interpretation for SIRVA).

1. Petitioner's prior condition.

There is no evidence in the medical records that petitioner had any history of pain, inflammation or dysfunction in her right shoulder prior to receiving the November 15, 2012 flu

vaccine. Further, respondent has not alleged that petitioner had any symptoms of shoulder injury prior to the receipt of the November 15, 2012 flu vaccine.

2. Petitioner's pain occurred within the specified time period.

A SIRVA Table injury requires a petitioner to demonstrate that the first symptom of shoulder pain occur within forty-eight hours of vaccination. 42 C.F.R. § 100.3(a)(XIV)(B).

The respondent argued that the petitioner fails to meet the SIRVA criteria because the "contemporaneous medical records do not support the onset of pain within forty-eight hours of vaccination." Resp. Rept. at 8; Resp. Post-Hearing Brief at 16. Respondent argues that petitioner first complained of right shoulder pain was fifteen weeks after vaccination. *Id.* Additionally, respondent stated that petitioner reported that the onset of pain and shoulder dysfunction was gradual over a three-month period of time, which is inconsistent with "the abrupt onset of pain that would lead one to seek medical assessment and treatment within 48 hours." Resp. Post-Hearing Brief at 16.

During the hearing, petitioner testified that she experienced "significant pain" in her right shoulder by the time she reached home after receiving the flu vaccine at her doctor's office on November 15, 2012. Tr. 49. She explained that as the night progressed, she felt "a lot of heaviness and pain," and she tried applying ice and taking pain medication to soothe the pain. *Id.* Petitioner testified that she thought the pain would go away, as some "shots are more painful than others." On cross-examination, petitioner was asked why she did not seek medical treatment sooner than February 2013, she explained that her pain was significant, but thought it was going to go away with the treatment of Tylenol, hot packs and ointment. Tr. 168-9. She stated that she thought her pain and limited range of motion in her right shoulder was going to be temporary and "resolve on its own." *Id.*

At petitioner's first appointment with Dr. Shah on February 28, 2013, he wrote that petitioner had complaints of pain in her right shoulder for three months. Pet. Ex. 3 at 1. He recorded petitioner's history as, "Flu shot-followed by flu 23rd November. Gradual onset-→worsening." *Id.* On July 17, 2013, petitioner had an appointment with Dr. Ari Geliebter, where petitioner attributed pain and limited range of motion to the flu shot she received in November 2012. Pet. Ex. 2 at 35. At an appointment with Dr. Steven Lager, petitioner reported that she had the flu vaccine in November 2012 and "developed acute shoulder pain and capsulitis." Pet. Ex. 5 at 6. On August 8, 2013, petitioner again associated the pain and stiffness in her right shoulder since receiving the flu vaccine in November 2012. Pet. Ex. 2 at 38.

Petitioner testified credibly that her pain began immediately after receiving the flu vaccine on November 15, 2012. Additionally, petitioner reported that her pain began immediately in her right shoulder after receiving the flu vaccination to multiple medical care providers consistently. Therefore, I conclude that petitioner's pain in her right shoulder began immediately after she received the flu vaccination on November 15, 2012.

3. Petitioner's pain and reduced range of motion is limited to the shoulder which she received the intramuscular flu vaccine.

As discussed above, I found that the November 15, 2012 flu was administered to her right arm. Based on the petitioner's testimony and the medical records, petitioner' vaccine-related symptoms were limited to her right shoulder.

Physical exams by petitioner's treating physicians consistently demonstrated that petitioner had reduced range of motion in her right shoulder compared to her left. For example, at petitioner's first physical therapy appointment in India on February 28, 2013, petitioner demonstrated reduced range of motion in her right shoulder on active range of motion, including flexion, abduction, internal rotation and external rotation, but her left shoulder active range of motion and strength was "within normal limits." Pet. Ex. 12 at 2. On July 26, 2013, at petitioner's appointment with Dr. Lager, petitioner again demonstrated reduced range of motion in her right arm on abduction, external rotation, flexion and internal rotation compared to her left side, which were within normal limits. Pet. Ex. 5 at 1. Petitioner was diagnosed with "severe right shoulder capsulitis," at this appointment. *Id.* On April 10, 2014, petitioner had an appointment with Dr. Wanich. Pet. Ex. 8 at 2. At this appointment, Dr. Wanich observed petitioner had reduced range of motion in her right upper extremity and diagnosed her with "right shoulder adhesive capsulitis." Pet. Ex. 6 at 4. The record demonstrates that petitioner's pain and reduced range of motion were limited to her right shoulder and there is no indication that petitioner experienced pain or limited range of motion in any area other than her right arm.

4. No other condition or abnormalities are present to explain petitioner's symptoms.

Petitioner's treating physicians diagnosed her with adhesive capsulitis, a diagnosis associated with SIRVA. Dr. Bodor stated, "I have found adhesive capsulitis (frozen shoulder) to be clearly documented in 56% of SIRVA claimants whose medical histories I have reviewed in the last few years. This is much higher than the 3-5% lifetime risk of frozen shoulder in the general population." Pet. Ex. 37 at 3. Dr. Bodor opined, "The vaccine was likely injected into [petitioner's] subdeltoid bursa and rotator cuff, which caused her immediate pain after the injection and worsened over time as the vaccine stimulated an inflammatory response and eventually adhesive capsulitis set in. Pet. Ex. 37 at 3.

He stated that, "In the weeks and months following her flu vaccination, [petitioner] developed adhesive capsulitis." *Id.* He observed that adhesive capsulitis can be secondary to trauma, rotator cuff tears, tendonitis, burns and neurologic disorders. *Id.* He opined that, "If frozen shoulder can be secondary to all of these conditions, then it would not be a leap to consider that it could also be secondary to SIRVA, which has components of acute and chronic injury and inflammation." *Id.*

Dr. Ring agreed that petitioner was correctly diagnosed with adhesive capsulitis. Resp. Ex. A at 3. However, he stated that, "Any pain that [petitioner] currently experiences in her shoulder would be caused by age-related rotator cuff tendinopathy." *Id.* Dr. Ring stated that, "[Petitioner's] adhesive capsulitis improved gradually over about 2 years, as expected, resulting

in full or near full shoulder motion as evidenced by the physical therapy visit on June 9, 2014." Resp. Ex. A at 2.

Dr. Ring observed that Dr. DiFelice, an orthopaedic surgeon, reviewed petitioner's 2016 MRI and stated, "MRI of the right shoulder performed at Infocus Diagnostics on 9/26/2016 was reviewed and demonstrates rotator cuff tendinosis." Resp. Ex. A at 4; Pet. Ex. 27 & 29 at 2. Dr. Ring interpreted Dr. DiFelice's notes from the appointment with petitioner on May 4, 2018 as, "In other words, it's clear from Dr. DiFelice's notes that the adhesive capsulitis is resolved and any residual symptoms are due to another problem: age-appropriate changes in the rotator cuff tendons. I agree with Dr. DiFelice's assessment." Resp. Ex. A at 4. However, the note from petitioner's appointment with Dr. DiFelice states, "[Petitioner] is a 53 y.o. female with right shoulder chronic rotator cuff syndrome, *possible related to flu shot*." Pet. Ex. 29 at 2 (emphasis added). Dr. DiFelice does not relate petitioner's rotator cuff syndrome to "age-related" changes, but instead raises the possibility that her rotator cuff syndrome is instead, related to the flu shot.

Further, Dr. Ring explained that, "Rotator cuff tendinopathy (impingement syndrome) is the change that occurs in the tendons that surround or "cuff" the head of the humerus….Those tendons change and thin with age…and can develop defects. This is usually present in some degree after the age of 40. Most of these changes are asymptomatic." Resp. Ex. A at 2. Dr. Ring's assessment is consistent with the Atanasoff article, which states, "…chronic shoulder pain with or without reduced shoulder joint function can be caused by a number of common conditions including, impingement syndrome, rotator cuff tear, biceps tendonitis, osteoarthritis and adhesive capsulitis. In many cases, these conditions may cause *no symptoms until provoked by trauma or other events."* Pet. Ex. 39 at 3 (emphasis added). The authors of the article state, "Therefore, some of the MRI findings in our case series, such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination synovial inflammation." *Id.*

Petitioner's right shoulder MRI did not occur until 2016 in the course of her injury, therefore it is difficult to know for sure when the partial tear of the rotator cuff occurred. However, given Dr. Bodor's opinion that the vaccine was likely injected into the subdeltoid bursa and the rotator cuff, it seems likely that this initial trauma to the rotator cuff and the bursa gave rise to the adhesive capsulitis from which she suffers. While there is no evidence that petitioner had rotator cuff tendinopathy prior to receiving the November 15, 2012 flu vaccination, even if she had age-related changes as asserted by Dr. Ring, the record is clear that petitioner did not experience any symptoms (pain or dysfunction) until after she received the flu vaccine on November 15, 2012.

Petitioner's course of pain and shoulder dysfunction is consistent with the findings described in the Atanasoff article. Therefore, the record demonstrates that no other conditions or abnormalities were present to explain petitioner's symptoms of right shoulder pain or dysfunction.

5. Petitioner has established a logical sequence of cause and effect showing the flu vaccine was the cause of her right shoulder injury.

In conclusion, petitioner's injury meets the criteria for a SIRVA injury and the clinical course of petitioner's injury mirrors a typical SIRVA injury. Therefore, the undersigned finds petitioner has demonstrated by preponderant evidence a logical sequence of cause and effect, satisfying *Althen* prong two.

D. *Althen* prong three: Petitioner has demonstrated a medically appropriate proximate temporal relationship between vaccination and injury.

Under *Althen* Prong Three, petitioner must establish a "medically acceptable temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281.

A SIRVA Table injury requires a petitioner to demonstrate that the first symptom of pain begins within forty-eight hours of vaccination. 42 C.F.R. § 100.3(a)(XIV)(B). Respondent argued, "The contemporaneous medical records also do not support the onset of pain within the specified time frame (within forty-eight hours of vaccination). Resp. Post-Hearing Brief at 16. Respondent stated that the first-time petitioner complained of right shoulder pain was fifteen weeks after vaccination and that the record indicates that petitioner "onset was gradual." *Id.* Respondent asserts that petitioner's failure to seek medical attention for her shoulder pain for approximately three months and the description that "onset was gradual" is "not consistent with the abrupt onset of pain that would lead one to seek medical assessment and treatment within 48 hours." *Id.*

As discussed above, petitioner testified credibly that she experienced pain in her right shoulder almost immediately after receiving the flu vaccine on November 15, 2012. Additionally, petitioner explained that she thought that the pain was going to subside and used home remedies to alleviate her pain. Tr. 168-9. Further, once petitioner sought treatment from medical providers, she consistently reported that her shoulder pain began immediately after she received the flu vaccination on November 15, 2012.

Considering the findings above, I conclude that petitioner's shoulder pain began within 48 hours of her November 15, 2012 flu vaccination. Therefore, petitioner has satisfied *Althen* prong three.

IV. CONCLUSION

Thus, for all the foregoing reasons, I find that petitioner established by a preponderance of the evidence that her November 15, 2012 flu vaccination was the cause-in-fact of her right shoulder injury. She is entitled to compensation. A separate damages order will be issued.

IT IS SO ORDERED.

s/ Thomas L. Gowen
Thomas L. Gowen
Special Master